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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/674,973	06/04/2001	Gustav Gaudernack	1702.401500	8016

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EXAMINER	
BORIN, MICHAEL L	

ART UNIT	PAPER NUMBER
1631	

DATE MAILED: 03/06/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
09/674,973	Gaudernack et al
Examiner	**Art Unit**
Michael Borin	1631

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☐ Responsive to communication(s) filed on _____.

2a) ☐ This action is **FINAL.** 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *35-73* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☐ Claim(s) _____ is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☒ Claims *35-73* are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

Part III DETAILED ACTION

This is a supplemental restriction requirement made *in lieu* of the previous requirement mailed 01/31/2003. Due to an inadvertent error, Examiner issued previous requirement drawn to set of claims as originally filed, rather than to the set of claims presented in the Preliminary amendment. The latter set of claims is now addressed in the following restriction requirement.

Claims 33-71 are submitted in the Preliminary amendment. Because original claims were claims 1-34, the new set of claims is renumbered as claims 35-73.

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in response to this action, to elect a single invention to which the claims must be restricted.

I. Claims 35-51, drawn to peptides and compositions thereof.

Claims 36-49 of this Group are further divided into following Groups:

Groups I.1-I.14 drawn to different peptides derived from unrelated genes.

Upon selection of one of the Groups from Groups I.1-I.14, claim ~~1~~ 35 will be addressed as linking claim.

II[1]. Claim 52, drawn to vaccine.

III[1]. Claim 53, drawn to method of use of protein of Group I for making pharmaceuticals.

IV[1]. Claim 54-56,72, drawn to method of use of protein of Group I for vaccination

V[1]. Claim 57-59,73 (in part), drawn to method of use of protein of Group I for treatment of cancer *in vivo*.

VI[1]. Claim 60, drawn to composition comprising other active ingredients in addition to protein of Group I.

VII. Claims 61-63,66-69, drawn to DNA and vector comprising thereof.

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[1]All groups reciting product of Group 1 are subject to restriction to groups .1-.14 similarly to product of Group I.

VIII. Claims 64, drawn to method of use of DNA of Group VII for making pharmaceuticals.

IX. Claims 65,71 (in part), drawn to *in vivo* treatment of cancer using DNA or vector comprising thereof.

X. Claim 65,71 (in part), drawn to *in vitro* treatment of cancer using DNA or vector comprising thereof.

XI. Claim 57-59,73 (in part), drawn to method of use of protein of Group I for treatment of cancer *in vitro*

The inventions listed as Groups I-XI do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: Group I is the technical feature that links Groups I-XI. Group I is not the contribution over the prior art because it is suggested by references cited in the International Search report issued in the preceding PCT case, as well as by plurality of references teaching peptide fragments. Therefore, the lack of unity is present because the linking technical feature is not a "special technical feature" as defined by PCT Rule 13.2.

VIII. Claims 62, drawn to method of use of DNA of Group VII for making pharmaceuticals.

IX. Claims 63,69 (in part), drawn to *in vivo* treatment of cancer using DNA or vector comprising thereof.

X. Claim 63,69 (in part), drawn to *in vitro* treatment of cancer using DNA or vector comprising thereof.

XI. Claim 55-57,71 (in part), drawn to method of use of protein of Group I for treatment of cancer *in vitro*

The inventions listed as Groups do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: Group I is the technical feature that links Groups I-XI. Group I is not the contribution over the prior art because it is suggested by references cited in the International Search report issued in the preceding PCT case, as well as by plurality of references teaching peptide fragments. Therefore, the lack of unity is present because the linking technical feature is not a "special technical feature" as defined by PCT Rule 13.2.

Group I and II are drawn to patentably distinct products which require differing characteristics. The vaccine composition requires different host, not required for polypeptide of Group I, has different pharmaceutical effect, and has separate enablement requirement.

Groups I.1-I.14 are drawn to peptides derived from unrelated genes, which peptides are independent and patentably distinct compounds since each of these compounds possess different structure, and/or physico-chemical properties,.and capable of separate manufacture and/or use. The correspondent methods of use are independent and/or distinct due to the use of different patentably distinct agents

Group VI is drawn to pharmaceutical composition comprising active agents not required in composition comprising protein of Group I. Accordingly, this group will require separate search and considerations.

Groups I and VII are separate and distinct because the inventions are directed to different chemical types regarding the critical limitations therein. For Group I, the critical feature is a polypeptide whereas for Group VII the critical feature is a polynucleotide. It is acknowledged that various processing steps may cause a polypeptide of group I to be directed as to its synthesis by a polynucleotide of Group VII, however, the completely separate chemical types of the inventions of Groups I

and VII supports the undue search burden if both were examined together. Additionally, polypeptides have been most commonly, albeit not always, separately characterized and published in the Biochemical literature, thus significantly adding to the search burden if examiner together, as compared to being searched separately. Also, it is pointed out that processing that may connect two groups does not prevent them from being viewed as distinct, because enough processing can result in producing any composition from any other composition if the processing is not so limited to additions, subtractions, enzyme actions, etc.

Groups III-V are drawn to distinct processes of using the product of Group I. The processes of groups III-V are distinct because the processes are not disclosed as usable together, and because none of the processes reasonably suggest the other two. Similarly, Groups VIII-X are drawn to distinct processes of using the product of Group VII. The processes of the groups are distinct because the processes are not disclosed as usable together, and because none of the processes reasonably suggest the other two. Groups X,XI, and V,IX are drawn to *in vitro* and *in vivo* methods of use, respectively.

Sequence Election Requirement Applicable to All Groups

In addition, each Group detailed above reads on a plurality of independent and/or patentably distinct sequences. Each peptide or nucleic acid sequence is independent and/or patentably distinct because they are unrelated compounds, there is no disclosed core structure required for a common utility, and because each of these compounds possess different structure and/or physico-chemical properties, and/or capable of separate manufacture and/or use. **For an elected Group the Applicants must further elect a single amino acid or nucleic acid sequence, such as those recited in claims 33 or 26,27. This is not an election of species requirement.**

MPEP 803.04 states:

> Nucleotide sequences encoding different proteins are structurally distinct chemical compounds and are unrelated to one another. These sequences are thus deemed to normally constitute independent and distinct inventions within the meaning of 35 U.S.C. 121. Absent evidence to the contrary, each such nucleotide sequence is presumed to represent an independent and distinct invention, subject to a restriction requirement pursuant to 35 U.S.C. 121 and 37 CFR 1.141 et seq.

Examination will be restricted only to a Group drawn to elected sequences.

Because these inventions are distinct for the reasons given above, and because of their recognized divergent subject matter, and the necessity for non-coextensive literature searches restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Borin whose telephone number is (703) 305-4506. Dr. Borin can normally be reached between the hours of 8:30 A.M. to 5:00 P.M. EST Monday to Friday. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Michael Woodward, can be reached at (703) 308-4028. The fax telephone number for this group is (703) 305-3014.

Any inquiry of a general nature or relating the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

February 20, 2003

MICHAEL BORIN, PH.D
PRIMARY EXAMINER

mlb